General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Saltley Pharmacy, 118 Washwood Heath Road, Saltley, BIRMINGHAM, West Midlands, B8 1RE

Pharmacy reference: 1038185

Type of pharmacy: Community

Date of inspection: 09/08/2021

Pharmacy context

This is a traditional community pharmacy situated next to a medical centre in the suburbs of Birmingham. The pharmacy dispenses NHS and private prescriptions. And it sells a small range of over-the-counter medicines. This was a targeted inspection in response to information that the pharmacy was dispensing private prescriptions on behalf of EU Meds Ltd, an online prescribing service, which was based outside of the UK regulatory framework. And not all standards were inspected during this visit.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

Follow this link to find out what the inspections possible outcomes mean

Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards not all met	1.1	Standard not met	The pharmacy does not identify and manage the risks associated with dispensing prescriptions generated by an online prescribing service operating outside of UK healthcare regulatory control. The pharmacy has not undertaken risk assessments to ensure that the supply of medicines which can be misused, abused or over-used to people is safe and clinically appropriate. And it does not have standard operating procedures in place for the provision of this service.
		1.2	Standard not met	The pharmacy cannot demonstrate that it audits and monitors the prescribing and supply of medicines via a third party online prescribing service to prevent misuse or abuse.
		1.8	Standard not met	The pharmacy does not have robust safeguards in place to address the risks of supplying certain medicines to vulnerable people who may be using the online prescribing service to obtain medicines which are not clinically appropriate for them and which could lead to patient harm.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy dispenses large quantities of medicines which can be abused, misused and overused. But members of the pharmacy team do not routinely refer to information provided by people or make clinical interventions. And the pharmacy is unable to provide assurances that relevant information or details about people's prescriptions are shared with other healthcare providers to support their ongoing care.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance **Standards not all met**

Summary findings

The pharmacy does not identify and manage risks associated with working with an online prescribing service which is based outside of the UK regulatory framework. And it is unable to demonstrate that it has robust safeguards in place to ensure that the supplies of medicines through this route are clinically appropriate and do not pose a risk of harm to people. The pharmacy has not completed relevant risk assessments before working with the online prescribing service to provide assurances that its working practices are safe. And it does not have relevant standard operating procedures in place for the provision of this service.

Inspector's evidence

A regular locum pharmacist was the responsible pharmacist (RP) on duty on the day of the visit. The correct RP notice was displayed in the pharmacy and the RP log had been completed. The RP records were kept in line with requirements. The RP said that the pharmacy had been providing a dispensing service for a third-party online prescribing service from mid-June 2021 to 6 August 2021. And the service had been suspended since then, as he was due to go on annual leave. Prior to commencing the service, the RP said that the pharmacy's director and a representative from the company that introduced the pharmacy to the online prescribing service had visited the pharmacy, to explain the service and provide assurances that the dispensing service was legitimate, and all the necessary checks had been undertaken. The RP said that the pharmacy was currently dispensing very few NHS prescriptions and he felt able to accommodate additional workload comfortably. There was no evidence that the pharmacy had downloaded or dispensed any private prescriptions from the online prescribing service on the day of the visit.

The pharmacy had been dispensing approximately 30 private prescription items a day and approximately 400 prescriptions had been dispensed since the service commenced. Most supplies to people were for medicines which are liable to abuse, misuse or overuse, including: opioid-based pain killers, Z-drugs, amitriptyline and modafinil. The website people used to access the prescribing service stated that the company was registered in United Arab Emirates, meaning that it was outside of UK healthcare regulatory oversight. The prescriber who was issuing prescriptions for the online service was registered in the European Economic Area (EEA). So, was also not subject to UK healthcare regulatory oversight.

The pharmacy was unable to provide evidence that it had completed a robust risk assessment to provide assurances that all the risks associated with the service had been identified and mitigated. And it did not have standard operating procedures in place for the provision of this service. The RP said that he had not completed any independent checks to verify the prescriber's credentials or to ensure that the prescriber was registered within their home country without restrictions. Or if the prescriber could lawfully issue online prescriptions to people living in the United Kingdom. The RP was largely reliant on assurances given to him by his director and the company representative who was involved in setting up the service. And he was not certain whether the director of the pharmacy had contacted their indemnity insurance providers to seek further advice. The RP said that he was not aware of the GPhC's distance-selling guidance as he didn't think it applied to their pharmacy.

People wishing to access the online prescribing service completed an online questionnaire as part of the

consultation process. The RP said that he occasionally checked the completed online questionnaires and most people had stated the main reason for using the online prescribing service was because they were unable to access their own GP services during the pandemic. The RP said that he felt this was a genuine reason, as his own patients were unable to make appointments throughout the pandemic with the surgery next door.

The pharmacy did not have any input into the prescribing decisions or make any clinical interventions to ensure that medicines supplied to people were clinically appropriate. The RP said that the online prescribing service checked the questionnaires and made all the necessary contact with people where appropriate.

The inspectors were unable to view any completed questionnaires as these were no longer available on the system once the medication had been dispatched. The RP said that he had on several occasions checked people's electronic prescribing service nomination on the computer to ascertain that he was supplying to genuine people. But it was his understanding that people's identity checks were all completed by the company who operated the prescribing platform.

The RP commented that he was aware that the medicines supplied were susceptible to abuse or overuse. He had indicated that he made some checks to make sure that the quantities prescribed were not excessive or that he was not making repeat supplies to people. However, he also commented that he had possibly made repeat supplies to a couple of people but that he was not unduly concerned as the quantities prescribed were not excessive. The pharmacy did not have any direct contact with the people it dispensed these medicines for to provide any additional counselling or review their use of medication. There were a couple of instances where people had tried to contact the pharmacy, but they were signposted to get in touch with the online prescribing service. The pharmacy did not inform people's GPs about the supplies it made. The RP said he wasn't sure if the online prescribing service liaised with people's GPs. And he had sought no additional evidence about this.

Private prescription records were kept electronically, and they were generally in line with requirements. And the pharmacy made entries of the supplies on its patient medication record system. The RP was not aware of any specific policies or procedures the online prescribing service had in place to safeguard vulnerable people and to help prevent unsafe supplies to people. And he had not thought about the risks associated with this type service, including the risks to vulnerable people who might be using the prescribing service to obtain medicines which were not clinically appropriate for them and which could lead to patient harm.

Principle 2 - Staffing ✔ Standards met

Summary findings

Members of the pharmacy team work well together and can manage their workload adequately.

Inspector's evidence

The RP and a qualified dispenser were working at the time of the visit. The pharmacy was very quiet, and the team were managing their workload adequately. The team appeared to work well together.

There was no evidence found that the pharmacy had downloaded or had dispensed any prescriptions on the day of the visit. The RP said that he personally did not have any financial gains or incentives from offering this service. And all the financial arrangements were between the online prescribing service and the director of the pharmacy.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are generally clean and adequate for the provision of healthcare services.

Inspector's evidence

The pharmacy was situated next to a medical centre and its entrance door was wide enough to accommodate people with mobility difficulties. The pharmacy's opening hours and a list of NHS services offered were advertised in the window. The pharmacy was of an average size and there was an adequate amount of storage and dispensing space available to work safely. But the dispensary itself was cluttered in places. And some fixtures and fittings appeared dated.

There was adequate lighting throughout the premises and the room temperature was suitable for storing medicines. The pharmacy stocked a small range of healthcare products, and pharmacy-only medicines couldn't be self-selected. A private consultation room was available for people wishing to have a confidential consultation with members of the pharmacy team. The premises were protected from unauthorised access when the pharmacy was closed.

The website for the online prescribing service which the pharmacy was associated with did not meet the GPhC's guidance for registered pharmacies providing services at a distance. The website allowed a prescription-only medicine and its quantity to be selected before there had been an appropriate consultation with a prescriber. This makes the process appear transactional and could mean that people may not always get the most clinically appropriate treatment.

Principle 4 - Services **Standards not all met**

Summary findings

The pharmacy does not always carry out enough checks to make sure that the medicines it supplies to people are safe and clinically appropriate. It cannot provide assurances that the prescriptions it dispenses on behalf of an online prescribing service are meeting legal requirements. And it cannot demonstrate that the online prescribing service shares information with a person's GP to make sure their health and wellbeing is protected. Members of the pharmacy team cannot provide assurances that undelivered medicines are securely handled and disposed of safely.

Inspector's evidence

People accessed the online prescribing service directly by going to a separate website operated by a third-party and the pharmacy did not advertise the prescribing service. The RP was not sure if people using the prescribing service had a choice of which pharmacy dispensed their prescription. And information about the pharmacies involved in dispensing and supplying medicines to people was not stated on the website.

As set out in Principle one, the medicines prescribed by the online service were almost exclusively for opioid-based painkillers, diazepam, Z-drugs, modafinil, and amitrptyline. The prescriptions seen indicated the prescriber was based in Frankfurt. And prescriptions appeared to be issued to people on the basis of an online questionnaire. The pharmacy was not aware what contact the prescriber had with patients beyond the questionnaire. The pharmacy did not routinely review the responses to the questionnaires as part of their clinical check. And the pharmacy had no evidence to show that the prescribing service was sharing relevant information about the medicines it prescribed with people's own GPs.

The pharmacy received the private prescriptions issued by the online prescriber via email. The prescriptions were received as a PDF attachment which was printed by members of the pharmacy team. It was unclear if the signature on the prescriptions met the requirements for an advanced electronic signature. Or what system there was in place to prevent the same prescription being dispensed by another pharmacy. Prescriptions were received together with pre-printed postage and dispensing labels. Dispensing labels included the name and address of the pharmacy and dosage instructions. A standard number of pre-printed dispensing labels were issued, regardless of the quantity supplied, which could create confusion and increase the risk of a dispensing incident. Team members initialled the pre-printed labels to keep an audit trail to show who had dispensed and checked the medication. And patient information leaflets were routinely supplied. Once the prescription had been dispensed, it was scanned into the website's system so that orders could be tracked.

Dispensed medicines were collected from the pharmacy by a driver for onward delivery by Royal Mail. The RP had not noticed that the return address for undelivered medicines on the packaging labels was for an address in Nottingham. This meant that the pharmacy was unable to verify that undelivered medicines were securely handled and disposed of safely. The pharmacy sourced most of its stock medicines from Lexon, DE and Alliance.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for the services it provides.

Inspector's evidence

Members of the pharmacy team had access to reference sources including a British National Formulary and internet access. Electrical equipment appeared to be in good working order. Computer systems were password protected and no confidential information was visible form the public area of the pharmacy.

What do the summary findings for each principle mean?

Finding	Meaning
✔ Excellent practice	The pharmacy demonstrates innovation in the way it delivers pharmacy services which benefit the health needs of the local community, as well as performing well against the standards.
✔ Good practice	The pharmacy performs well against most of the standards and can demonstrate positive outcomes for patients from the way it delivers pharmacy services.
✔ Standards met	The pharmacy meets all the standards.
Standards not all met	The pharmacy has not met one or more standards.